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September 29, 2021

VIA CM/ECF

Hon. Thomas J. McAvoy
Senior U.S. District Judge
United States District Court
Northern District of New York
Federal Building & U.S. Courthouse
15 Henry Street
Binghamton, New York 13901

Re: Regeneron Pharmaceuticals, Inc. v. Novartis Pharma AG et al., Case No. 1:21-cv-01066

Dear Judge McAvoy:

Along with Weil, Gotshal & Manges LLP, we represent the plaintiff, Regeneron Pharmaceuticals, Inc. ("Regeneron"), in the above-referenced action, as well as in the potential related patent action (Case No. 1:20-cv-690-TJM) (the "Patent Case") before this Court. As your Honor is aware, Regeneron's case asserting antitrust and tort claims against Novartis Pharma AG, Novartis Pharmaceuticals Corporation, and Novartis Technology LLC (collectively, "Novartis") and Vetter Pharma International GMBH ("Vetter"), has been transferred to you from the Southern District of New York by order of Judge Alison J. Nathan (Case No. 1:20-cv-05502-AJN) (the "Antitrust Case"). For the Court's convenience, Regeneron provides the following summary and update on the newly transferred Antitrust Case.

A. Regeneron Brought Antitrust and Tort Claims Against Novartis and Vetter

As previously reported to Your Honor in the Patent Case, Regeneron filed an antitrust action against Novartis and an additional defendant, Vetter, on July 17, 2020, alleging multiple violations of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2. Antitrust Case, ECF No. 1. On January 25, 2021, Regeneron filed an amended complaint based upon confidential agreements and communications between Novartis and Vetter that were produced during the course of fact discovery. Antitrust Case, ECF Nos. 87-88.

By way of overview, Regeneron's case challenges the anticompetitive conduct of Novartis and Vetter to restrain competition in and monopolize the U.S. market for anti-vascular endothelial growth factor ("anti-VEGF") treatments in prefilled syringes ("PFS"). PFS are overwhelmingly preferred for anti-VEGF treatments as they provide multiple benefits over vials, including increased safety, reduced risk of endophthalmitis, and more accurate dosing. Regeneron alleges

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Also Admitted In: Massachusetts

that Defendants have taken numerous actions in furtherance of their concerted and secretive efforts to insulate LUCENTIS PFS from competition, including from Regeneron's innovative EYLEA PFS. Novartis's and Vetter's anticompetitive licensing scheme and tortious conduct ultimately caused the EYLEA PFS launch to be delayed, enabling Novartis to retain its LUCENTIS PFS monopoly in the anti-VEGF PFS market with patients being overcharged and doctors and patients being forced to use a product they do not prefer. *See* Antitrust Case, ECF No. 88 ¶¶ 210–217. Unless stopped, this anticompetitive behavior has caused, and will continue to cause, substantial harm not only to Regeneron, but also to the millions of elderly U.S. patients suffering from severe and degenerative eye diseases. Regeneron's amended complaint asserts the following five claims:

> **Count I: Attempted Monopolization Against Novartis Under Section 2 of the Sherman Act.** Novartis committed *Walker Process* fraud in procuring U.S. Patent No. 9,220,631 (the "'631 patent") by purposefully omitting material prior art from the U.S. Patent and Trademark Office ("USPTO") and then knowingly enforcing that fraudulently procured patent against Regeneron with the specific intent to monopolize the U.S. anti-VEGF PFS market. Antitrust Case, ECF No. 88 ¶¶ 218–232.
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> **Count II: Attempted Monopolization Against Novartis Under Section 2 of the Sherman Act.** In addition to its enforcement of the fraudulently procured '631 patent, Novartis further attempted to monopolize the U.S. anti-VEGF PFS market by undertaking additional anticompetitive conduct including an unlawful patent licensing scheme with Vetter. *Id.* ¶¶ 233–250.
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> **Count III: Unreasonable Restraint of Trade Against Novartis and Vetter Under Section 1 of the Sherman Act.** Regeneron brings a stand-alone cause of action independent of the '631 patent against Novartis and Vetter for restricting competition in the U.S. anti-VEGF PFS market by trying to force anti-VEGF PFS rivals (like Regeneron) into an exclusive long-term filling arrangement with Vetter so that Novartis and Vetter could limit PFS supplies. *Id.* ¶¶ 251–275.
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> **Count IV: Attempted Monopolization Against Novartis Under Section 2 of the Sherman Act.** Novartis also committed *Walker Process* fraud in procuring the '631 patent by deliberately omitting required Vetter inventor(s) from its patent application and then knowingly enforcing that fraudulently obtained patent against Regeneron with the specific intent to monopolize the U.S. anti-VEGF PFS market. *Id.* ¶¶ 276–284.
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> **Count V: Tortious Interference With Regeneron's Contract With Vetter.** As an additional stand-alone claim independent of the '631 patent enforcement, Novartis fraudulently concealed Vetter employees' inventorship of the '631 patent in order to sabotage Regeneron's ownership rights under Regeneron's then-existing EYLEA PFS contract with Vetter. *Id.* ¶¶ 285–294.

Regeneron is seeking a declaration that the '631 patent is unenforceable, along with injunctive relief and actual damages (automatically trebled under the antitrust laws and punitive damages for tortious conduct) caused by Novartis's and Vetter's anticompetitive conduct, plus

Regeneron's attorneys' fees and costs in having to defend Novartis's meritless '631 patent infringement cases in both the NDNY and U.S. International Trade Commission ("ITC")[1] and in prosecuting the Antitrust Case.

B. Antitrust Discovery Progressed Far in the Antitrust Case

Following the filing of Regeneron's initial complaint in the Antitrust Case, Novartis and Vetter moved to stay discovery pending resolution of their Rule 12(b)(6) motions to dismiss. Judge Nathan heard oral argument on the stay motion and denied Defendants' request on November 2, 2020, during the parties' Initial Pretrial Conference. Antitrust Case, ECF No. 65. Judge Nathan instead entered a Case Management Plan and Scheduling Order for the case to move forward. *Id.* Fact discovery thereafter progressed expeditiously.

In particular, the parties have engaged in extensive document and written discovery over the course of the last 10 months. Pursuant to the governing schedule in the Antitrust Case, ECF No. 133, all parties substantially completed their productions of documents. And with a negotiated cross-use agreement from the ITC proceeding, combined with the productions in the Antitrust Case, the record currently comprises over 800,000 documents totaling over ten million pages. *See* Antitrust Case, ECF No. 102. The parties also engaged in substantial written discovery with Regeneron, Novartis, and Vetter all serving interrogatories prior to the August 2, 2021 deadline, and various parties serving requests for admission, Rule 30(b)(6) deposition notices, and third-party subpoenas for documents.

With written discovery and document productions largely completed, the parties are scheduled to begin depositions of fact witnesses. The parties are in agreement with respect to the number of and protocol for depositions to proceed in the Antitrust Case, and the Court entered the parties' stipulation for depositions on September 10, 2021. Antitrust Case, ECF No. 138. The parties also recently agreed to a three-month extension of the schedule to complete fact depositions and were preparing to file a proposed order prior to the issuance of Judge Nathan's transfer order. The governing schedule in the Antitrust Case, ECF No. 133, and the parties' agreed three-month extension set forth the following deadlines:

EVENT	CURRENT DATE	AMENDED DATE
Deadline for Production of Privilege Logs	October 18, 2021	October 18, 2021
Deadline to Serve Requests for Admission	November 1, 2021	January 31, 2022
Close of Fact Discovery	December 2, 2021	March 2, 2022
Opening Expert Reports Due	January 13, 2022	April 13, 2022
Production of Documents and Data Considered in Experts' Reports	January 20, 2022	April 20, 2022
Rebuttal Expert Reports Due	March 10, 2022	June 8, 2022

[1] *In re Certain Pre-Filled Syringes For Intravitreal Injection & Components Thereof*, U.S. ITC Pub. 715158 (July 21, 2020).

Production of Documents and Data Considered in Experts' Reports	March 17, 2022	June 15, 2022
Reply Expert Reports Due	April 14, 2022	July 13, 2022
Production of Documents and Data Considered in Experts' Reports	April 21, 2022	July 20, 2022
Close of Expert Discovery	May 16, 2022	August 15, 2022
Summary Judgment/*Daubert* Motions Due	June 27, 2022	September 26, 2022
Summary Judgment/*Daubert* Oppositions Due	August 8, 2022	November 7, 2022
Summary Judgment/*Daubert* Replies Due	September 8, 2022	December 7, 2022

Based on the parties' agreement regarding the schedule, Regeneron expects to submit a proposed joint amended scheduling order for this Court's consideration.

C. Coordinated Antitrust Discovery With the Patent Case Should Continue Without Delay in the NDNY

Novartis has repeatedly taken the position, including before this Court, that discovery in the Antitrust Case overlaps with the required discovery for the Patent Case and thus should be coordinated. As Novartis stated in the parties' August 12, 2021 Case Management Plan for the Patent Case, "[a]s matters of both efficiency and fairness, both fact and expert discovery in the cases should be coordinated[.]" Patent Case, ECF No. 73. In furtherance of such coordination, the parties have executed and filed several cross-use stipulations in the Antitrust Case with both the ITC and Patent Case to avoid any potentially duplicative discovery and to reduce the burden on all parties. *See, e.g.*, Stipulated Orders Establishing Protocols for Production and Cross-Use of Discovery Previously Produced Before the ITC, Antitrust Case, ECF Nos. 102, 132; Stipulation and Order Regarding Depositions, Antitrust Case, ECF No. 138. Regeneron will continue to work in good faith with Novartis and Vetter to coordinate discovery of Regeneron's Antitrust Case with the Patent Case in order "to secure the just, speedy, and inexpensive determination of [this] action and proceeding." Fed. R. Civ. P. 1.

D. Rule 12(b)(6) Motions Filed in the Antitrust Case

In transferring the Antitrust Case to the NDNY, Judge Nathan did not resolve Novartis's and Vetter's Rule 12(b)(6) motions to dismiss. Regeneron opposes those motions and believes the substantial progress of the case and investment by the parties accomplished as a result of the denial of Novartis's and Vetter's discovery stay motion counsels in favor of the Court resolving this dispute on a full factual record. Nevertheless, Regeneron provides the following summary of filings and events for the Court's convenience and for the sake of completeness.

On October 19, 2020, Novartis and Vetter moved to dismiss Regeneron's complaint under Rule 12(b)(6). Antitrust Case, ECF Nos. 55, 58. Regeneron opposed. Antitrust Case, ECF Nos. 45, 66. Regeneron in turn filed its amended complaint on January 25, 2021, based on critical discovery produced by Vetter confirming many of Regeneron's allegations. Antitrust Case, ECF Nos. 87–

88. Novartis and Vetter thereafter filed renewed 12(b)(6) motions to dismiss. Antitrust Case, ECF Nos. 89, 94. Regeneron again opposed the pre-answer motions to dismiss on March 22, 2021, and Novartis and Vetter filed their replies on April 12, 2021. Antitrust Case, ECF Nos. 105, 114, 117. To minimize re-briefing, the parties' incorporated by reference certain arguments made in the Rule 12(b)(6) briefing pertaining to Regeneron's original complaint.

The parties also have submitted supplemental letters and updates in the Antitrust Case. On April 7, 2021, Novartis submitted a letter regarding the withdrawal of its ITC proceeding to exclude EYLEA PFS from the U.S. market. Antitrust Case, ECF No. 109. Regeneron submitted a response on April 12, 2021, explaining that Novartis abandoned its ITC proceeding after the independent, neutral Office of Unfair Import Investigations representing the public interest filed its 203-page brief (the "ITC Staff Brief"). Antitrust Case, ECF No. 112. As Regeneron explained, the ITC Staff Brief adopted many of Regeneron's positions, including that the '631 Patent is invalid under a "clear and convincing" evidence standard. *Id.* The ITC Staff Brief corroborates Regeneron's allegations in the Antitrust Case concerning Novartis's inequitable conduct before the USPTO, and is additional, persuasive authority confirming the plausibility of Regeneron's Antitrust Case. *Id.* Given its importance to the case, the parties submitted the ITC Staff Brief for the court's consideration. Antitrust Case, ECF Nos. 112-1, 122.

If this Court would prefer paper copies of the Rule 12(b)(6) briefing and a confidential version of the ITC Staff Brief, we would be happy to work with Defendants to submit a single set of materials.

Finally, no oral argument was held on the Rule 12(b)(6) motions in the Antitrust Case while they were pending before Judge Nathan. To the extent it would be helpful for Your Honor, Regeneron would welcome the opportunity to present argument on these motions to the Court.

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Thank you for the Court's time and attention. We are available at the Court's convenience to discuss any issues relating to either the Antitrust Case or the Patent Case, and would welcome the opportunity to appear at a status conference to discuss next steps in these matters.

Respectfully submitted,

Douglas J. Nash

cc: Counsel of Record (*via CM/ECF*)